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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,468	07/02/2003	Jingwu Z. Zang	057186.000003	5234
7590 Dr. Benjamin Adler c/o Adler & Associates 8011 Candle Lane Houston, TX 77071		09/22/2009	EXAMINER JUEDES, AMYE	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 09/22/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/612,468

**Applicant(s)**

ZANG ET AL.

**Examiner**

AMY E. JUEDES

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10, 13, 14, 42 and 44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 13, 14, 42 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### DETAILED ACTION

1. Applicant's amendment and remarks, filed 1/8/07 and 5/26/09, are acknowledged.

Claims 1-9, 11-12, 15-41, and 43 have been cancelled.

Claims 10, 13-14, 42, and 44 have been amended.

Claims 10, 13-14, 42, and 44 are pending and are under examination.

2. Upon reconsideration, and in view of Applicant's amendment and remarks, only the following rejection remains.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 10 stands rejected under 35 U.S.C. 102(a) as being anticipated by GenPept Accession number CAD67333, Feb. 2003, as evidenced by Oxford University Press, "peptide" definition.

As set forth previously, The CAD67333 reference teaches an amino acid sequence having the amino acid sequence of SEQ ID NO: 4 of the instant application (see residues 92-98 in particular). Since the Oxford dictionary defines a peptide as any compound with two or more amino acids linked together, the sequence taught by CAD67333 is a peptide. It is noted that claims 11 and 13-14 are included since the patentability of a product does not depend on its method of production. Therefore, the fact that the instant peptide is derived from the CDR3 region does not render it patentably distinct from the peptide taught by CAD67333. CAD67333 has taught a peptide identical in structure to the instantly claimed peptide.

Applicant's arguments filed 1/8/07 have been fully considered, but they are not persuasive.

Applicant argues that CAD67333 specifically defines the disclosed sequence as a protein, and that the examiner is using the Oxford dictionary definition of the term "peptide" to refute the specifically stated definition of the amino acid sequence of CAD67333 as a protein. Thus, Applicant concludes that CAD67333 does not teach an isolated "peptide", as recited in the instant claims.

The instant specification does not define the term "peptide". Moreover, the terms "peptide" and "protein" can be used interchangeably (see for example, U.S. Patent 5,846,722, column 6, line 34). Thus, the sequence disclosed by CAD6733 can be considered a peptide.

5. The following are new grounds of objection and rejection.
6. Claim 13 is objected to because of the following informalities: The claim recites a peptide encoded by a fragment of a CDR3 of a T cell receptor gene with a DNA sequence of SEQ ID NO: 2. As written it is not clear if SEQ ID NO: 2 encodes the fragment or the T cell receptor gene. Appropriate correction is required.
7. Claim 44 is objected to for being dependent on cancelled claim 43. For the purposes of examination, it is being assumed that claim 44 should depend from claim 42.
8. The following is a quotation of the first paragraph of 35 U.S.C. 112:  

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-14, 42, and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification provides insufficient evidence that the peptide of SEQ ID NO: 4 can function as a vaccine in an individual suffering from rheumatoid arthritis or as a pharmaceutical composition to suppress pathogenic T cell response in an individual suffering from rheumatoid arthritis

The specification disclosure is insufficient to enable one skilled in the art to

practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

*In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. With these teachings in mind, an enabling disclosure, commensurate in scope with the breadth of the claimed invention, is required.

The instant claims are drawn to a vaccine or pharmaceutical composition comprising the peptide of SEQ ID NO: 4, wherein said peptide is to be used for vaccination/suppression of T cell responses in subjects with rheumatoid arthritis. SEQ ID NO: 4 represents a fragment of a pathogenic TCR from a rheumatoid arthritis subject. TCR peptides have been used in the art as vaccines from suppressing pathogenic T cell responses in autoimmune diseases such as rheumatoid arthritis (see Vandembark et al., 2001, of record). However, the ability of a TCR peptide to function as a vaccine is highly unpredictable, and dependent on many factors including MHC binding of the peptide, ability to induce Th2 cytokine producing regulatory T cells, immunogenicity of the peptide, and the immune status of the subject (see Vandembark

et al., page 715 in particular). Effective TCR peptide vaccines typically are 20-40 amino acids in length, and function by inducing a TH2 T cell response which suppresses the pathogenic T cells (see Vandenbark et al.). However, the peptide of the instant claims comprises only 7 amino acids. A 7 amino acid peptide would not be expected to bind to MHC I (see Janeway and Travers, MHC class I binding peptides are at least 8 amino acids, while MHC class II binding peptides are at least 13 amino acids). Thus, the ability of the TCR peptide to function as a vaccine in rheumatoid arthritis would be highly unpredictable, since it would not be able to induce any type of T cell response in the absence of MHC binding. Thus, based on the unpredictability of the art, the instant specification must provide a sufficient and enabling disclosure for one of skill in the art to use the peptides as claimed.

However, the specification does not provide any guidance or examples regarding the use of the peptide of SEQ ID NO: 4 as a vaccine in subjects with rheumatoid arthritis. The specification merely discloses that the sequence is expressed by TCRs from subjects with rheumatoid arthritis. Thus, given the unpredictability of the art and the lack of guidance by the instant specification, it would require undue experimentation to use the peptide as claimed.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,773,218.

The '218 patent teaches a peptide of SEQ ID NO: 104. Said peptide comprises the sequence of SEQ ID NO: 4 of the instant application, except for a single amino acid difference. Since SEQ ID NO: 104 of the '218 patent comprises 5 contiguous amino acids in common with SEQ ID NO: 4 of the instant application, it comprises "an" amino acid sequence of SEQ ID NO: 4, or is encoded by "a" DNA sequence of SEQ ID NO: 2,

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as recited in the instant claims. The '218 application also teaches the in vivo use of peptides for producing antibodies or for modulating T cell activation (i.e. a "vaccine", see column 7 and 9-10, in particular).

Thus, the reference clearly anticipates the invention.

10. No claim is allowed. Claims 42 and 44 are free of the art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 7am to 3:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy E. Juedes

Patent Examiner

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Patent Examiner, Art Unit 1644

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